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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,159	08/08/2003	J. Mark Weber	065382-0006	2929

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,159	WEBER ET AL.	
	Examiner	Art Unit	
	Iqbal H. Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The instant Office Action is a supplemental restriction requirement. The previous Office action mailed on 3/21/2007) [a restriction requirement for a process for producing biologically active compounds]. This supplemental requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the plurality of claimed patentably distinct inventions.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 2-3, 4-5, and 27, drawn to a method of increasing the production of rapamycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 120.

II. Claim(s) 2-3, 27, drawn to a method of increasing the production of immunosuppressant FK520, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 117.

III. Claim(s) 2-3, 27, drawn to a method of increasing the production of immunosuppressant ascomycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method

comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 118.

IV. Claim(s) 4-5, 27, drawn to a method of increasing the production of antifungal agent candicidin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 117.

V. Claim(s) 4-5, 27, drawn to a method of increasing the production of antifungal agent soraphen, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 117.

VI. Claim(s) 6-7, 27, drawn to a method of increasing the production of antiparasitic agent avermectin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 117.

VII. Claim(s) 8-11, 27, and 31-34, drawn to a method of increasing the production of antibiotic either polyketide or macrolide biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 117.

VIII. Claim(s) 12-14, 27, 30, and 33-34, drawn to a method of increasing the production of animal feed promotant monensin A and B, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription, classified in class 435, subclass 120.

IX. Claim(s) 2-3, 4-5, and 28-29, drawn to a method of increasing the production of rapamycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 120.

X. Claim(s) 2-3, 28-29, drawn to a method of increasing the production of immunosuppressant FK520, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 117.

XI. Claim(s) 2-3, 28-29, drawn to a method of increasing the production of immunosuppressant ascomycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 118.

XII. Claim(s) 4-5, 28-29, drawn to a method of increasing the production of antifungal agent candicidin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 117.

XIII. Claim(s) 4-5, 28-29, drawn to a method of increasing the production of antifungal agent soraphen, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 117.

XIV. Claim(s) 6-7, 28-29, drawn to a method of increasing the production of antiparasitic agent avermectin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 117.

XV. Claim(s) 8-11, 28-29, 30, and 31-34, drawn to a method of increasing the production of antibiotic either polyketide or macrolide biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 117.

XVI. Claim(s) 12-14, 28-29, drawn to a method of increasing the production of animal feed promotant monensin A and B, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription such that it does not encode an enzymatically active protein, classified in class 435, subclass 120.

XVII. Claim(s) 2-3, 24-26, drawn to a method of increasing the production of rapamycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 120.

XVIII. Claim(s) 2-3, 24-26, drawn to a method of increasing the production of immunosuppressant FK520, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 117.

XIX. Claim(s) 2-3, 24-26, drawn to a method of increasing the production of immunosuppressant ascomycin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 118.

XX. Claim(s) 4-5, 24-26, drawn to a method of increasing the production of antifungal agent candicidin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 117.

XXI. Claim(s) 4-5, 24-26, drawn to a method of increasing the production of antifungal agent soraphen, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 117.

XXII. Claim(s) 6-7, 24-26, drawn to a method of increasing the production of antiparasitic agent avermectin, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 117.

XXIII. Claim(s) 1, 8-11, 15-23, 24-26, drawn to a method of increasing the production of antibiotic either polyketide or macrolide biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 117.

XXIV. Claim(s) 12-14, 24-26, drawn to a method of increasing the production of animal feed promotant monensin A and B, a biologically active compound, in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing level of cofactor coenzyme B12 by inhibiting the transcription of cob gene, classified in class 435, subclass 120.

Claims 1 and 15-23 link(s) inventions I - XXIV. The restriction requirement of the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1 and 15-23. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

2. The methods of groups I-XXIV are unrelated and patentably distinct. Group I-VIII are drawn to a method of increasing the production of a various biologically active compound in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of inhibiting the activity of methylmalonyl-CoA mutase by reducing said mutase transcription. The method comprising the steps of inhibiting the activity of methylmalonyl-CoA mutase of Group IX-XVI are drawn to a method of increasing the production of a various biologically active compound in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, Group XVII-XXIV are drawn to a method of increasing the production of a various biologically active compound in a cell wherein the biologically active compound is derived at least in part from methylmalonyl-CoA, the method comprising the step of reducing the coenzyme B12 production by inhibiting cob gene encoding adenosyltransferase transcription. Because methods of Groups I-XXIV are unrelated and patentively distinct as they comprise unrelated steps, as use different products and produce different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. In addition, examining all the groups would require Patent and non-Patent literature databases, which would impose a serious search burden to the Examiner.

This application also contains claims directed to patentably distinct methods of producing distinct antibiotics species of biologically active compounds as recited in Groups VII, XV and XXIII. If applicants elect either Group VII or XV or XXIII, one of the species should be elected.

The biologically active compounds of antibiotic either polyketide or macrolide produced in the method are:

Erythromycin, tylosin, niddamycin, spiramycin, oleandomycin, methymycin, neomethymycin, narbomycin, pokromycin, or lankamycin. The methods of producing distinct biologically active compounds of antibiotics either polyketide or macrolide as recited in Group VII, XV and XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are patentively distinct and they comprise unrelated steps, as use different products and produce different effects.

Applicant is required under 35 U.S.C. 121 and 372 to **elect a single disclosed species** for prosecution on the merits to which the claims shall be restricted (i.e. either Group VII or XV or XXIII) if no generic claim is finally held to be allowable.

Because these species are distinct for the reasons given above and have acquired a separate status, election of species for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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